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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,195	12/02/2003	Shoichi Ozaki	13240.004CN1	5902

23369 7590 09/29/2006

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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/726,195	OZAKI ET AL.	
	Examiner	Art Unit	
	Nora M. Rooney	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *10-12* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. In view of the amendment submitted on 12/02/2003, the restriction mailed on 08/08/2006 is hereby withdrawn. The new restriction requirements are set forth below.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 10, drawn to a method for diagnosing an autoimmune disease comprising detecting one or more antibodies by contacting a reagent comprising at least one polypeptide antigen or fragment thereof selected from the HMG-1 family represented by SEQ ID NOs 1, 3, 4 and 5, classified in class 435, subclass 7.1.

II. Claim 10, drawn to a method for diagnosing an autoimmune disease comprising detecting one or more antibodies by contacting a reagent comprising at least one polypeptide antigen or fragment thereof selected from the HMG-2 family represented by SEQ ID NOs 2, 6, 7, 8, 9, 10 and 11, classified in class 435, subclass 7.1.

III. Claims 10-11, drawn to a method for diagnosing an autoimmune disease comprising detecting one or more antibodies by contacting a reagent comprising at least one polypeptide antigen or fragment thereof selected from the HMG-2 family represented by SEQ ID NOs 2, 6, 7, 8, 9, 10 and 11; and at least one polypeptide antigen or fragment thereof selected from the HMG-1 family represented by SEQ ID NOs 1, 3, 4 and 5, classified in class 435, subclass 7.1.

IV. Claim 12, drawn to a kit for diagnosing an autoimmune disease comprising a first antigen selected from the group consisting of a polypeptide or fragment thereof selected from the HMG-1 family represented by SEQ ID NOs 1, 3, 4 and 5; and a second antigen selected from the group consisting of a polypeptide or fragment thereof selected from the HMG-2 family represented by SEQ ID NOs 2, 6, 7, 8, 9, 10 and 11.

3. Groups I-III are different methods. A method of detecting an antibody using different polypeptides differs with respect to ingredients, method steps and endpoints. Therefore, each method is patentably distinct.

4. Groups IV and III are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the different polypeptides in Groups IV can be used for generation of monoclonal antibodies, in addition to the methods of detecting recited.

5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various

methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

Species Election

6. Irrespective of whichever group applicant may elect, applicant is further required under 35 U.S.C. 121: (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held allowable and (2) to list all claims readable thereon including those subsequently added.

A. If Group I is elected, applicant is required to elect:

1.) a polypeptide or fragment of a single species as recited in claim 10 having SEQ ID NO 1, 3, 4 or 5; and

The polypeptides differ with respect to their structures, expression, modes of action and physicochemical properties. Thus, each polypeptide species represents patentably distinct subject matter.

2.) a single autoimmune disease from the group consisting of rheumatoid arthritis, human systemic lupus erythematosus, Sjogren's syndrome, Behcet's disease, primary biliary cirrhosis, microscopic polyangitis/ polyarteritis nodosa, ulcerative colitis, Chron's disease or autoimmune hepatitis.

The pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

B. If Group II is elected, applicant is required to elect:

1.) a polypeptide or fragment of a single species as recited in claim 10 having SEQ ID NO 2, 6, 7, 8, 9, 10 or 11; and

The polypeptides differ with respect to their structures, expression, modes of action and physicochemical properties. Thus, each polypeptide species represents patentably distinct subject matter.

2.) a single autoimmune disease from the group consisting of rheumatoid arthritis, human systemic lupus erythematosus, Sjogren's syndrome, Behcet's disease, primary biliary cirrhosis, microscopic polyangitis/ polyarteritis nodosa, ulcerative colitis, Chron's disease or autoimmune hepatitis.

The pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

C. If Group III is elected, applicant is required to elect:

1.) a polypeptide or fragment of a single species as recited in claim 12 having SEQ ID NO 1, 3, 4 or 5 and a polypeptide or fragment of a single species having SEQ ID NO 2, 6, 7, 8, 9, 10 or 11; and

The polypeptides differ with respect to their structures, expression, modes of action and physicochemical properties. Thus, each polypeptide species represents patentably distinct subject matter.

2.) a single autoimmune disease from the group consisting of rheumatoid arthritis, human systemic lupus erythematosus, Sjogren's syndrome, Behcet's disease, primary biliary cirrhosis, microscopic polyangitis/ polyarteritis nodosa, ulcerative colitis, Chron's disease or autoimmune hepatitis.

The pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added

after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper

restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 23, 2006

Maher M. Haddad
MAHER M. HADDAD
PATENT EXAMINER

Nora M. Rooney, M.S., J.D.

Patent Examiner

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